



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,492	11/03/2003	John D. Brennan	571-886	3236
1059	7590	05/02/2007		
BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER SKIBINSKY, ANNA	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 05/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,492

Applicant(s)

BRENNAN ET AL.

Examiner

Anna Skibinsky

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7 and 9-21 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Applicants

Applicant's amendment to claim 1 is acknowledged.

Election/Restrictions

Claims 4 and 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/04/2006

Claims 1-3 and 5-21 are under consideration.

Drawings

The drawings are objected to. Figures 1, 4 and 6 not decipherable because the details of the figures can not be seen and is not clear what is meant to be shown by the figures. Figures 4(a) and (b) and 6 appear as solid black boxes. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary,

the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

PRIOR ART REFERENCE 1

Claims 1-3, 9, 11-18 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Um et al. (Pub No. US2003/0124371; priority date Nov. 8, 2001).

2. The prior art of Um et al. teaches a microarray where more than 100,000 different probe sequences can be bound to distinct special locations where each spot corresponds with a gene (paragraph 0002). Um teaches that a hydrogel can be used to

Art Unit: 1631

create an adsorbent layer on a biochip (paragraph 0017). The three-dimensional network (i.e. matrix as in claim 1) of the gel can be used to immobilize (i.e. entrap, as in claim 1) polypeptides by allowing an analyte solution to penetrate (i.e. entrapped within the matrix, as in claim 1) the three-dimensional structure (paragraphs 0063 and 0064).

The prior art of Um thus anticipates claims 1 and 21.

3. As in instant claim 2, the prior art teaches polymeric hydrogels for immobilizing analytes, where hydrogels are a type of sol-gel (paragraph 0009).

4. As in instant claims 3 and 9, polyol silanes and bis-silanes are taught as components of the hydrogel (paragraphs 0133-0135)

5. As in instant claims 11-13, the prior art teaches two component hydrogel systems composed of crosslinked polymers and copolymers (paragraph 0014), explaining that hydrogels are water-swellaable (paragraph 0017) and contain several moieties. The hydrogel has water a absorbent layer that includes copolymers (paragraph 0019, lines 13-15; paragraph 0048; paragraph 0068, lines 13-14)

6. As in instant claims 14 and 15, a moiety composing the hydrogel may contain glycerol or polyethylene glycol (paragraph 0068, lines 27-29).

7. As in instant claims 16 and 17, the material forming the substrate includes glass or metals (paragraph 0097, lines 1-3 and lines 13-15; and paragraph 0122).

8. Instant claim 18 recites cleaning the glassUm et al. teaches washing with water and buffer (paragraphs 0236-0238) as well as washing and drying (paragraph 0231), thereby anticipating claim 18.

PRIOR ART REFERENCE 2

Claims 1-3, 5-7, 16-18 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Preininger (Pub No. US2003/0040008; priority date April 12, 2000).

9. Preininger teaches immobilizing or binding analytes such as DNA, nucleic acids, proteins, peptides and enzymes and others to solid surfaces including biochips (paragraphs 0001, 0003, and 0017). Additionally, more biochips and microarrays for immobilizing DNA are taught (paragraphs 0020-0021). A variety of analytes are taught to attach to the surface in a spatially precise manner (paragraph 0030). Preininger teaches a variety of three-dimensional network forming materials for the immobilization of analytes, including swelling materials such as hydrogels (paragraph 0024), for example polyvinyl alcohol (0036). In particular, Preininger teaches that biomolecules such as enzymes, antibodies, microorganisms and oligonucleotides can be immobilized (i.e. entrapped) by embedding in (i.e. entrapped within, as in claim 1) polyvinyl alcohol, which has a large, porous surface (paragraph 0036). Thus, the prior art anticipates the limitations of claims 1 and 21.

10. As in instant claims 2-3 and 5-7, Preininger also teaches arrays made of various polymeric silanes and dextrans (paragraph 0024). Additionally, dextrans as a hydrogel, a type of sol gel, is taught (paragraph 0024, lines 9-12).

11. As in instant claims 16 and 17, the surface of the material may be glass (paragraph 0018).

12. As in instant claim 18, Preininger teaches washing the substrate with hybridizing solution (paragraphs 0036 and 0038).

RESPONSE TO ARGUMENTS

Applicant's arguments filed 1/30/2007 have been fully considered but they are not persuasive.

Applicants have amended claim 1 to recite "two or more components of a protein-based system entrapped within the matrix" and argue that Um et al. do not teach the entrapment of a multi-component protein based system within a biomolecule-compatible matrix (Remarks, page 8, lines 17-20).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., entrapment of a multi-component protein based system, as argued on page 8 of the response) are not recited in the rejected claim(s). Rather, claim 1 recites that "two or more components of a protein based system are entrapped within the matrix," which is not equivalent because applicants argument is directed to an entrapped *system* while the claim 1 recites *components* which are entrapped.

In addition, Um et al. do teach two or more components of a protein based system entrapped within a matrix. Um et al. teaches that a hydrogel can be used to create an adsorbent layer on a biochip (paragraph 0017). The three-dimensional network (i.e. matrix as in claim 1) of the gel can be used to immobilize (i.e. entrap, as in claim 1) polypeptides by allowing an analyte solution to penetrate (i.e. entrapped within the matrix, as in claim 1) the three-dimensional structure (paragraphs 0063 and 0064). The prior art of Um thus anticipates claims 1 and 21.

Applicants argue (Remarks, page 9, lines 21-24) that Preininger do not teach the entrapment of a multi-component protein based system within a biomolecule-compatible matrix.

As in the above response, claim 1 recites that "two or more *components* of a protein based system are entrapped within the matrix," which is not equivalent to the entrapment of a system, as argued by Applicant.

Furthermore, as stated in the previous Office Action (Response to Arguments, filed 11/02/07; page 6, lines 17-20) and reiterated in the above rejection, Preininger does teach entrapped components of a protein based system within a matrix because. Preininger teaches a variety of three-dimensional network forming materials (i.e. matrix) for the immobilization of analytes, including swelling materials such as hydrogels (paragraph 0024), for example polyvinyl alcohol (0036). In particular, Preininger teaches that biomolecules such as enzymes, antibodies, microorganisms and oligonucleotides can be immobilized (i.e. entrapped) by embedding in (i.e. entrapped within, as in claim 1) polyvinyl alcohol, which has a large, porous surface (paragraph 0036).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3, 5-7, 10, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preigninger as applied to claims 1-3, 5-7, 16-18 and 21 above, in view of Rubino (US Patent 6,584,259) and further in view of Ramsey (US Patent 6, 376, 181).

11. Preigninger teaches a sol gel matrix (Preigninger, paragraph 0024, lines 9-12) for the immobilization of biomolecules. Preigninger further teaches a glass microarray (Preigninger, paragraph 0018) for the immobilization of biomolecules.

Preigninger does not teach preparation of the sol-gel using sodium silicate as required by claim 10, nor does he teach the modification of the glass microarray with glycidoxymethylpropyltrimethoxysilane (GPS), as required by claims 19 and 20 of the instant application.

Rubino however teaches using sodium silicate to make glass sol-gel (col. 2, line 62 to col. 3, line 5).

Ramsey et al. teaches modification of a glass microarray surface with GPS (col. 3, lines 55-65).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used sodium silicate as taught by Rubino et al. to make sol-gel as taught by Preigninger since Rubino et al. teaches the formation of sol-gel (col. 2, line 65-67). One of ordinary skill in the art would have been motivated to use sodium silicate an ingredient in the formation of the sol-gel because Rubino teaches that sodium silicate is used to form inorganic adhesiveness in sol-gel (Rubino, col. 1, line 65 to col. 2, line 20) and works well with almost any sol-gel formulation (Rubino, connecting paragraph of col. 2 and col. 3).

In addition, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the glass substrate surface of Preigninger with GPS as taught by Ramsey et al. One of skill in the art would have been motivated to use GPS because Ramsey et al. teach that oligonucleotides probes can be immobilized on glass surfaces with a linker such as GPS (col. 3, lines 5-65). Since Preigninger teaches the immobilization of nucleotides and biomolecules on the glass substrate with a linker (paragraphs 0015-0017), the modification of the glass with the GPS as taught by Ramsey et al. would be obvious.

Claims 1-3, 9- 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Um et al. as applied to claims 1-3, 9, 11-18 and 21 above, in view of Rubino (US Patent 6,584,259) and further in view of Ramsey (US Patent 6, 376, 181).

Art Unit: 1631

11. Um et al. teaches a sol gel matrix (Um et al., paragraph 0009) for the immobilization of biomolecules. Um et al. further teaches a glass microarray (Um et al., paragraph 0097, lines 1-3 and lines 13-15; and paragraph 0122) for the immobilization of biomolecules.

Um does not teach preparation of the sol-gel using sodium silicate as required by claim 10. Um further does not teach the modification of the glass microarray with glycidoxymethyltrimethoxysilane (GPS), as required by claims 19 and 20 of the instant application.

Rubino however teaches using sodium silicate to make glass sol-gel (col. 2, line 62 to col. 3, line 5).

Ramsey et al. however teaches the modification of the glass microarray surface with GPS (col. 3, lines 55-65).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used sodium silicate as taught by Rubino et al. to make sol-gel as taught by Um et al. since Rubino et al. teaches the formation of sol-gel (Rubino et al., col. 2, line 65-67) made with sodium silicate. One of ordinary skill in the art would have been motivated to use sodium silicate an ingredient in the formation of the sol-gel because Rubino teaches that sodium silicate is used to form inorganic adhesiveness in sol-gel (Rubino, col. 1, line 65 to col. 2, line 20) and works well with almost any sol-gel formulation (Rubino, connecting paragraph of col. 2 and col. 3).

It would also have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the glass substrate surface of Um et

Art Unit: 1631

al. with GPS as taught by Ramsey et al. One of skill in the art would have been motivated to use GPS because Ramsey et al. teach that oligonucleotide probes can be immobilized on glass surfaces with a linker such as GPS (col. 3, lines 5-65). Since Um et al. teaches the immobilization of biomolecules on the glass substrate with a cross-linker (paragraph 0077), the modification of the glass with the GPS as taught by Ramsey et al. would be obvious.

Response to Arguments

13. Applicant's arguments filed 2/22/07 have been fully considered but they are not persuasive.

14. Applicants argue (page 10, lines 17-23) that the deficiency of Preininger et al. is not made up by either Rubino or Ramsay et al.

15. As in the reply to Applicants above, the 102(e) rejection by Preininger et al. is maintained. Therefore, the 103(a) rejection, over Preininger et al. in view of Rubino and further in view of Ramsey et al. is maintained.

16. Applicants argue (page 11, lines 14-19) that the deficiency of Um et al. is not made up by either Rubino or Ramsay et al.

17. As in the reply to Applicants above, the 102(e) rejection by Um et al. is maintained. Therefore, the 103(a) rejection, over Um et al. in view of Rubino and further in view of Ramsey et al. is maintained.

Objections

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
4/30/07